

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231*Ch*

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/365,065	07/30/99	COLLINS	D 10847/002001

MARK S ELLINGER
FISH & RICHARDSON PC
60 SOUTH SIXTH STREET
SUITE 3300
MINNEAPOLIS MN 55402

HM12/0614

EXAMINER

ZEMAN, R
ART UNIT PAPER NUMBER

1645

21

DATE MAILED:

06/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/365,065

Applicant(s)
Collins

Examiner
Robert A. Zeman

Art Unit
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 6, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 and 1
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Art Unit: 1645

DETAILED ACTION

Continued Prosecution Application

The request filed on 4-6-2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/365,065 is acceptable and a CPA has been established. An action on the CPA follows.

The amendment filed 4-6-2001 is acknowledged. Claims 1, 2 and 20-21 have been amended. Claims 1-21 are pending and currently under examination.

Information Disclosure Statement

The Information Disclosure Statement filed on 4-6-2001 is acknowledged. The listed references have been considered in this Office Action. An initialed copy of form PTO-1449 is enclosed herein.

Claim Rejections Withdrawn

The rejection of claims 1-21 under 35 U.S.C. 103(a) as being unpatentable over Kortright et al.(U.S. Patent 4,870,003) in view of Jackson et al. (U.S. Patent 5,776,709) is withdrawn in view of Applicant's arguments and the most recent amendments to the claims.

Art Unit: 1645

New Grounds of Rejection

Claim Objections

Claim 21 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Said claim recites the limitation of "a label or package insert". Specific disclosure of a label or insert and the information contained therein carries no patentable weight.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor et al. (U.S. Patent 5,627,026-- IDS-14) in view of Jackson et al. (U.S. Patent 5,776,709).

Applicant claims methods and kits for simultaneously detecting both members of a binding pair in a complex utilizing fluorescent labels. The methods consists of coating a solid phase

Art Unit: 1645

reagent with “capture” antibodies specific for one member of the binding pair; contacting said particles with test sample to bind first member of the binding pair (if present); adding fluorescently labeled antibodies specific first member of the binding pair and fluorescently labeled antibodies specific for the remaining member of the binding pair; and measuring labels using flow cytometry.

O'Connor et al. disclose a method of detecting both members of a binding pair (antigen and antibody, for example) utilizing antibodies conjugated to different fluorescent labels.

O'Connor et al. further disclose that their method can be used to detect any “pair of molecules which have a specific binding affinity for each other e.g. hormones and hormone receptors and biotin and avidin” (see column 1 lines 23-27). O'Connor et al. further disclose that the labels used in their method can be any detectable label including “a radioisotope, an enzyme, or a **fluorophore**” (see Column 2, lines 1-3) and that said method can be used to simultaneously test for antigens and antibodies associated with a viral infection (see Column 4, lines 23-26).

O'Connor et al. disclose many variations of their method including one wherein the antigen and antibody of a binding pair are simultaneously detected in a biological sample through the use of antibodies/antigens bound to a solid support (latex beads) and labeled secondary antibodies (see column 2, lines 27-39). O'Connor et al. further discloses kits for performing said assays (see column 3, lines 8-29). The instant claims recite the use of a label on a kit. The use of such a label is standard practice and hence would be obvious to one of skill in the art. O'Connor et al. differs from the claimed invention in that they do not explicitly disclose the use of flow cytometry to measure the labeled antibodies. Jackson et al disclose the benefit of using multiple fluorescent

Art Unit: 1645

labels as opposed to other labeling techniques (such as enzyme labels). Multiple fluorescent labels “provide(s) a means for obtaining a maximum amount of information with the minimal sample manipulation, resulting in time savings both in sample preparation and instrument data acquisition” The method allows detection of two or more subpopulations depending on the number of fluorochrome-labels used. Therefore, it would have been obvious to one of skill in the art to use the fluorochrome labeling disclosed by Jackson et al. in the methods disclosed by O’Connor et al. in order to reap the benefits of direct measurement of each label (and hence the each binding pair member) as well as the reduction in sample preparation and data acquisition.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

Art Unit: 1645

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.



DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman

June 13, 2001